



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94705d

Public Health Service

Food and Drug Administration  
College Park, MD 20740

JAN 22 2004

WARNING LETTER  
ONPLDS 01-04

BY CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Thomas S. Wade  
CEO  
Russell Stover Candies, Inc.  
4900 Oak Street  
Kansas City, Missouri 64112-2702

Dear Mr. Wade:

The Food and Drug Administration (FDA or the Agency) has reviewed the labels for Russell Stover® LOW CARB Mint Patties, LOW CARB Toffee Squares, and LOW CARB Pecan Delights. As a result of our review, we have determined that these labels cause the above products to violate the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 321 *et seq.*) and implementing regulations in Title 21 of the Code of Federal Regulations (CFR). The specific violations relate to misbranding and are explained below.

First, these products are misbranded under section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)) because their labels bear the claim "LOW CARB" (meaning low in carbohydrate). Section 403(a)(1) provides that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. In determining whether labeling is misleading, the Agency takes into account representations made or suggested by a statement, among other things (*see* 21 U.S.C. 321(n)). A comparison of the carbohydrate content of your products to comparable products, based upon the reference amount customarily consumed (RACC) of 40 grams (g) (*see* 21 CFR 101.12(b)) for these types of products, reveals that they contain the same or similar amounts of carbohydrate. For example, the amount of total carbohydrate per RACC in your LOW CARB Mint Patties is 27.1 g, compared to a range of 23.2-33.8 g in comparable commercial products. Similarly, the amount of total carbohydrate per RACC is 22.9 in both your LOW CARB Toffee Squares and LOW CARB Pecan Delights, compared to ranges of 15.8-25.6 g and 18.8-24 g, respectively, in comparable commercial products. Thus, these products are not lower in carbohydrate than other comparable commercial products. Consequently, the "LOW CARB" claim is false and misleading and therefore violates section 403(a)(1).

Second, these products are misbranded under section 403(a)(1) because their labels bear the claim "CARBS PER PIECE\*" with an amount, "0.1," "0.2" and "1.2" for LOW CARB Mint Patties, LOW CARB Toffee Squares, and LOW CARB Pecan Delights, respectively. This claim appears in a circle on the principal display panel of each of these products. It is false and misleading under sections 201(n) and 403(a)(1) of the Act because the declared level of total carbohydrate in the Nutrition Facts box is 19 grams for two Mint Patties, and 16 grams for two Toffee Squares or two Pecan Delights.

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Finally, the labels for these products also bear the claim "ZERO SUGAR CARBS" but the Nutrition Facts box does not include a declaration of sugars content, as required by 21 CFR 101.9(c)(6)(ii).

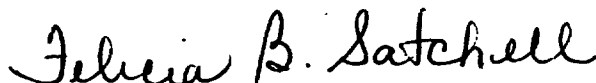
The above violations are not meant to be an all-inclusive list of deficiencies for the labeling of these products or any other product your firm manufactures or labels. It is your responsibility to ensure that all of your products are labeled in compliance with the laws and regulations enforced by FDA.

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Copies of revised labels for the products should be submitted. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820), 5100 Paint Branch Parkway, College Park, Maryland 20740.

Sincerely yours,



Felicia B. Satchell  
Director  
Food Labeling  
and Standards Staff  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition